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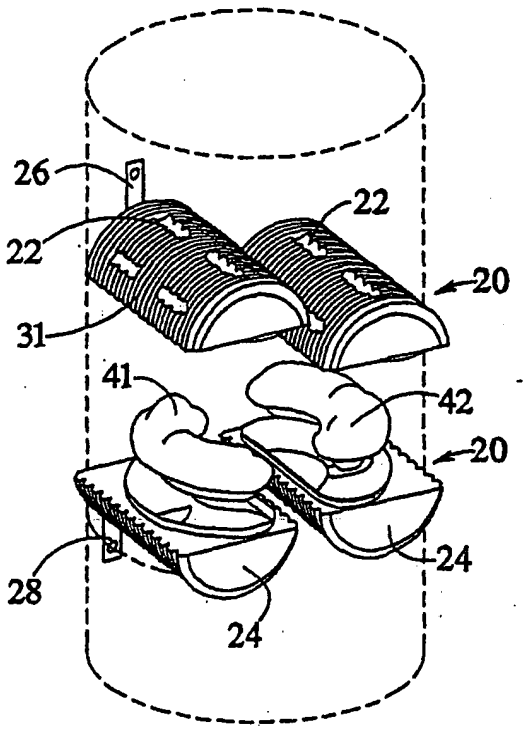
(54) Title: CYLINDRICAL HEMI-LUNAR PARALLEL ARRAY THREADED DISC PROSTHESIS

(57) Abstract

A small profile, cylindrically or conically shaped prosthetic disc device (20) is provided. The device housing is comprised of two longitudinally split hollow halves (22, 24), between which is contained a hemi-lunar shaped resilient body (41) which may be of a polymeric type, or it may contain hydrogel. This hemi-lunar disc lies in concave surfaces (51) located on the interior of each side of the split cylindrical housing. The housing halves (22, 24), even under maximum physiological loads, do not contact one another directly. Threads (31) on the exterior surface (30) of the cylindrical housing (20) facilltates insertion, and retention in theprepared bone opening.



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# SPECIFICATION

## TITLE

## CYLINDRICAL HEMI-LUNAR PARALLEL ARRAY THREADED DISC PROSTHESIS

This invention relates to the design and use of a unique disc prosthesis for the lumbar and thoracic spine. By placing one hemi-lunar prosthetic disc within a cylindrical housing of metal, ceramic, or polymeric material, (the housing being separated into two longitudinally separated sections) a small profile prosthesis can be created which will allow placement of the device through a small surgical opening into an intervertebral space within a human spine.. By placing two such cylindrical threaded devices in parallel into the intervertebral space, each housing containing one hemi-lunar resilient disc, positioned so that the convex portions of the two separately housed discs approximate an interrupted circle or toroid, a full range of motion of the functional spinal unit (FSU) can be achieved.

If the hemi-lunar material possesses resilient, viscoelastic properties, and if the housing is split so that the internally placed hemi-lunar disc maintains separation of the upper and lower housing members, a cushioning effect can be obtained.

The hemi-lunar disc material is substantially surrounded by concave surfaces formed within the housing, which are contoured to articulate with the upper and lower surface shapes of the hemi-lunar disc, so that the housings containing the discs may slide and /or rotate over the surface of the hemi-lunar discs to provide for joint space motion.

The exterior surface of the split housing is threaded so that it can be screwed into a pre-tapped hole of appropriate size formed in confronting surfaces of adjacent intervertebral bones or bodies. The upper sectional of the threaded housing engages the cephalad vertebral body's inferior endplate and cancellous bone, and the other section of the threaded housing engages the opposing superior endplate and cancellous bone of the caudal vertebral body when the implant is fully inserted.

Threaded cylindrical housings of differing sizes can be installed in a parallel array so as to allow for appropriate spinal column curvature when inserted into the spine and alined from a lateral direction.

U.S. Patent 5,674,296 is incorporated by reference.

## BACKGROUND OF THE INVENTION

Degenerative disc disease, including disc herniation, may produce disabling symptoms of local pain, radiculopathy or myelopathy in an otherwise clinically stable spine, which may be unresponsive to non-surgical treatment. Several surgical treatments are available to address the symptoms of degenerative disc disease when non- invasive therapies are not effective. These surgical treatments include decompression, discectomy and fusion. These treatments, and in particular the discectomy and fusion procedures, provide relief of clinical symptoms but they do not restore normal or near normal range of motion or cushioning to the affected functional spinal unit (FSU). This can result in acceleration of the degenerative process in spinal discs adjacent to the original surgical operation site. This degenerative process can, in turn, require additional surgical intervention.

Open surgery and endoscopic techniques are often used to provide access to the intervertebral disc space. Posterior, postero-lateral, and anterior approaches allow placement of instrumentation to facilitate exposure of the degenerated disc and the insertion of bone grafts or fusion cages to accomplish bony fusion.

Because of anatomical structure considerations and instrument size restrictions associated with minimally invasive surgical techniques in the spine, the insertion of a functional disc prosthesis equal in size to the natural disc creates risks due to mechanical interferences with critical vascular structures.

It is the general object of this invention to provide a functional disc prosthesis which provides for a full range of motion of the FSU and for cushioning between two adjacent vertebrae while maintaining stability, intervertebral body spacing and lordosis.

More specifically it is an object of the invention to provide a disc prosthesis having a small or narrow profile. The novel exemplary prosthesis is cylindrical in exterior shape, and is comprised of two longitudinally split halves. Each housing half is separated from the other at all times by a hemi-lunar resilient body contained therein, and is strong enough to support the loads to which it shall be subjected during the activities of daily living. The housing contains a concave articulation recess capable of mating with the hemi-lunar resilient body placed between the two disc halves, and provide geometry which allows sliding and/or rotational motion.

The cylindrical housing is threaded on its exterior for ease of introduction into, and mechanical stability in, a prepared space in the opposing vertebrae of the FSU. The housing is configured to fit the restrictions imposed by the limited anatomical space available for the surgical placement of the implant, and is small so as to allow implantation procedures and instrumentation such as those used in an endoscopic procedure.

It is a further object of the invention to provide cylindrical housings of differing size, and resilient bodies contained within, so that when the cylindrically shaped prostheses units are used in parallel, they facilitate proper positioning of opposing vertebrae.

Another object is to obviate the need for a second surgical site for bone graft harvesting as may be required in spinal fusion procedures.

And it is a further object of the invention to provide a flexible containment barrier or sheath to completely surround and enclose the space occupied by the resilient body between the two cylindrical housing halves, so as to contain lubricant and debris.

Still another object of the invention is to provide a disc prosthesis which will permit motion between the housing halves.

A further object of the intention is to provide a disc prosthesis which will provide for cushioning between the housing halves.

It is a still further object of the invention to provide a disc prosthesis which may be used alone or in parallel array with similar prostheses.

Another object of the invention is to have ports in the housing for the introduction of a lubricant for the nucleus and housing interior. The ports can be sealed with a plug, screw or other device.

Other objects and advantages of the invention will become apparent to those skilled in the art upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

## DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded view of two of the novel prostheses arranged in parallel array.

Figure 2 is a top plan view of the prostheses shown in figure 1.

Figure 3 is a sectional view taken substantially in the plane of line 3 - 3 in figure 2.

Figure 4 is a sectional view taken substantially the plane of line 4 - 4 in figure 3.

Figure 5 is an isometric view of a housing half.

Figure 6 is a top plan view of the housing half shown in figure 5.

Figure 7 is a side elevation view of the housing half shown in figures 5 and 6.

Figure 8 is a sectional view taken substantially in the plane of line 8 -8 in figure 7.

Figure 9 is a developed end view taken substantially in the plane of line 9 – 9 in figure 7.

Figure 10 is a top plan view of the housing half shown in figures 6 and 7.

Figure 11 is a fragmentary view of a portion of the edge of the housing half shown in figure 8.

Figure 12 is a top plan view of an alternative embodiment of the hemi-lunar disc.

Figure 13 is an end view of the alternate embodiment hemi-lunar disc shown in figure 12.

While the invention will be described in connection with preferred embodiments, it will be understood that it is not intended to limit the invention to these embodiments. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

To accomplish the objectives set out above, the novel exemplary disc prosthesis 10 includes, as shown in figures 1 - 4, a cylindrical housing 20. The housing 20 includes an upper half housing 22 and a lower half housing 24. In the embodiment shown in figure 1, an upper fixator wing 26 is welded or otherwise associated with the upper half housing 22, and a lower fixator wing 28 is similarly welded or otherwise associated with the lower half housing 24. These wings 26, 28 can be used to stabilize the prosthesis to bone, as suggested in U.S. Patent 5,674,296. The wings 26, 28 can be omitted, as suggested in figures 2 - 10.

As particularly shown in figures 2 and 4, a hemi-lunar shaped viscoelastic disc 41 is interposed between the upper half housing 22 and the lower half housing 24 to

maintain the housing halves separate from one another and to provide for a defined range of motion. The shape of the hemi-lunar disc 41 can be partially bi-convex discoid. The disc provides stability and limitation against excessive motion of the housing halves and prosthesis during motion of the functional spinal unit. The disc can have a relatively soft and resilient interior and a relatively hard end durable exterior. Alternatively, the disc element 41 may be made of a suitable hydrogel.

An alternative embodiment of the hemi-lunar disc is shown in figures 12 and 13. To provide additional stability to the implant, this resilient disc 60 takes the general appearance of an elongated hemisphere. Corresponding modifications are made to the interior of the housing halves 22, 24.

When implants 20 are used in parallel array as suggested and figures 1 and 2, the arrangement of these semi-lunar disks 41, 42 resembles an interrupted toroid.

The housing 20 has an exterior surface 30 which bears a screw thread shape 31. This screw thread shape 31 is continuous, and is contiguous from housing half 22 to housing half 24 so that the disc prosthesis can be screwed into a pre-tapped intervertebral space hole formed within between two adjacent vertebrae as, for example, in the human spine. If desired, recesses 35 can be formed to permit bone ingrowth and further stabilization of the device. The housing 20 shape can be that of a right cylinder or it can be conical.

In accordance with one aspect of the invention, this small or thin profile prosthesis 20 can be implanted in the spine through a small surgical opening. One device 20 may be used, or by placing two such devices 20 in parallel as suggested in figures 1 and 2, a full range of motion of the functional spinal unit (FSU) can be achieved. If the discoid material possesses resilient, viscoelastic properties similar to the removed natural disk, with the housing being split or otherwise open on its sides with the internally placed hemi-lunar disc maintaining the separation of the upper and lower housing members 22 and 24, , a cushioning effect may also be realized.

If desired, a flexible sheath or seal 50 can be attached to the housing halves, as by a retaining wire or circlage band 41 tensioned in a groove 46, as suggested in figures 3, 8 and 11, and in U.S. Patent 5,674,296.

As suggested in figures 5 and 10, each hemi-lunar disc 41, 42 can be carried in

a concave surface 51 formed or contained within the housing, and contoured to accept the upper and lower surface shape of the hemi-lunar disc 41 so that the housings 20 each comprising the two or more halves or paired shells 23, 24 may slide and/or rotate over the surface of the discs 41, 42 to provide for joint space separation and motion.

As noted above, the exterior surface of the split housing 20 has a threaded formation so that it may be screwed into a pre-tapped hole of appropriate size at an intervertebral disc space. When properly screwed into place, the upper half of the threaded housing engages the cephalad vertebral bone inferior endplate and the other half 24 of the threaded housing engages the opposing superior endplate of the caudal vertebral bone when fully inserted.

The device may be inserted via open or minimally invasive techniques including endoscopy, or by a variety of known surgical approaches where adequate anatomical space is available. Though the prosthesis is inserted as a single threaded cylindrical unit, its final position is such that one half of the housing is left exclusively in contact with the endplate and cancellous bone of one vertebral body and the other in the exclusive contact of the opposing vertebral body endplate and cancellous bone. The hemi-lunar resilient bodies between the cylindrical housing halves allow movement by providing for sliding and rotating in multiple directions and cushioning in response to physiological loads placed upon them. When housing cylinders of different size are at used in parallel, intervertebral spacing can be varied to achieve desired vertebrae positional relationships.

By varying the shapes of the housings, and the contained sliding discs, a non-parallel array can be utilized, especially in cases of significant anatomical interferences.

I CLAIM:

1. A disc prosthesis comprising, in combination, a cylindrical or conical housing, the housing including an upper half and a lower half and a resilient, viscoelastic disc interposed between the upper half housing and the lower half housing to maintain the housing halves separate from one another.

2. A disc prosthesis according to claim 1 wherein said disc is hemi-lunar in shape.

3. A disc prosthesis according to claim 1 wherein the disc is partly surrounded by a concave surface formed within said housing.

4. A disc prosthesis according to claim 1 wherein said housing has a threaded exterior surface bearing a screw thread shape.

5. A disc prosthesis according to claim 4 wherein said screw thread is continuous, and is contiguous from housing half to housing half so that the disc prosthesis can be screwed into a pre-tapped intervertebral space hole.

6. A disc prosthesis according to claim 1 wherein recesses are defined in said housing to permit bone ingrowth.

7. A disc prosthesis according to claim 1 including a wing member attached to each of the upper and the lower half housing members, the wings permitting the housing halves to be affixed to spinal vertebrae.

8. A disc prosthesis affixed within a human spine, the prosthesis comprising an upper half housing engaging the cephalad vertebral bone inferior endplate and cancellous bone; a lower half housing engaging the caudal vertebral bone superior end plate and cancellous bone; and a resilient disc interposed between the housing halves.

9. A disc prosthesis according to claim 8 wherein said disc is partly surrounded by a concave surface formed within one of said housing halves.

10. A disc prosthesis according to claim 8 wherein each housing half has a threaded exterior surface.

11. A disc prosthesis comprising, in combination, a hollow cylindrical or partially conical housing, the housing including two separate halves and at least one prosthetic disc located between the two housing halves.

12. A disc prosthesis according to claim 11 in which each housing half is at least partly defined, in its interior, by a concave surface.

13. A plurality of disc prostheses located within a human spine , each prosthesis comprising an upper half housing engaging a cephalad bone inferior endplate; a lower half housing engaging a caudal vertebral bone superior endplate; and at least one resilient disc interposed between each of the housing halves.

14. A plurality of disc prostheses according to claim 13, each prosthesis having a threaded exterior surface.

15. A plurality of disc prostheses according to claim 14 wherein each prosthesis has recesses defined in its exterior surface to permit bone ingrowth.

16. A viscoelastic hemi-lunar prosthetic disc for use in a human spinal implant, the prosthetic disc having convex external surfaces for sliding engagement with concave surfaces formed on the interior of rigid upper and lower half housings

17. The disc of claim 16 wherein said disc has a relatively soft and resilient interior and a relatively hard and durable exterior.

18. A disc prosthesis comprising, in combination, a housing, the housing having an exterior surface defining a general continuous thread formation, the housing including at least two rigid, confronting and complimentary parts, the prosthesis further comprising at least one resilient, viscoelastic hemi-lunar disc interposed between the housing parts to maintain the housing parts separate from one another but to provide cushioning between the housing parts and to permit limited motion between the housing parts.

19. A disc prosthesis according to claim 18 wherein the housing thread is adapted to engage the bone of adjacent vertebral bodies.

20. A disc prosthesis according to claim 18 including a sheath attached to said housing halves.

21. A disc prosthesis according to claim 18, the disc having a partial bi-convex discoid shape.

22. A disc prosthesis according to claim 1, including a sealable portal for introduction of a lubricant.

23. A disc prosthesis according to claim 1, further including a sheath interconnecting the housing halves.

FIG. 1

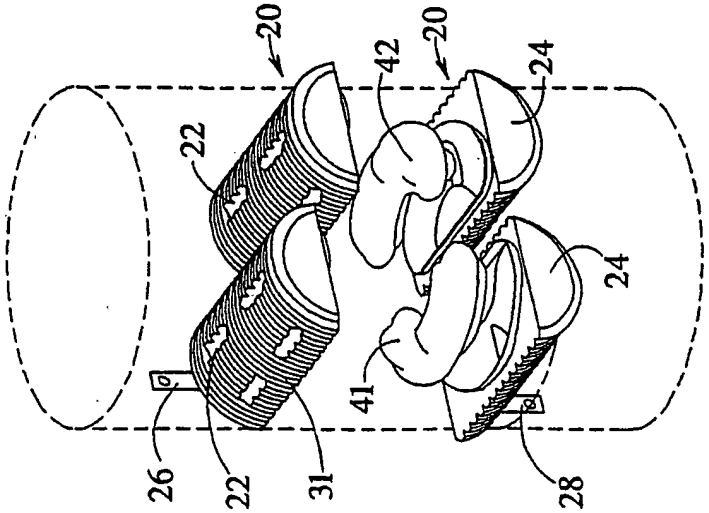



FIG. 2

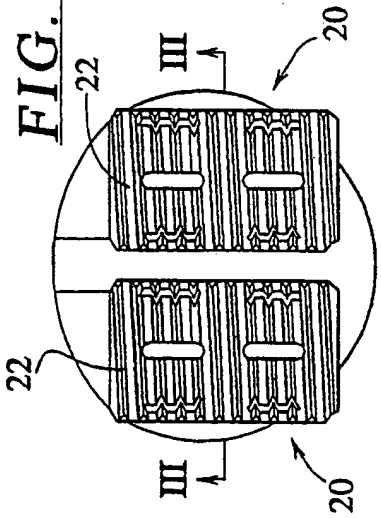



FIG. 3

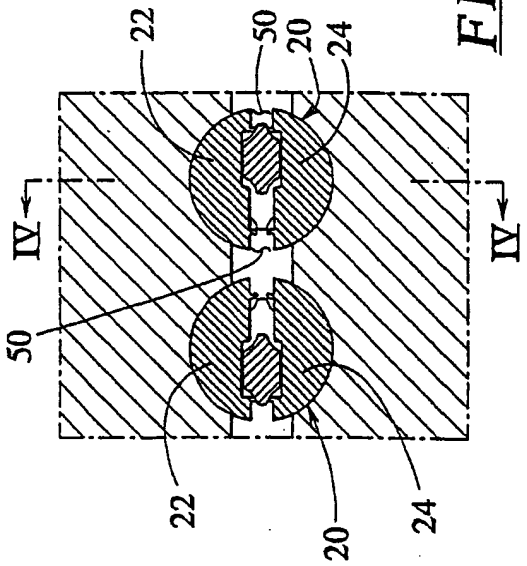
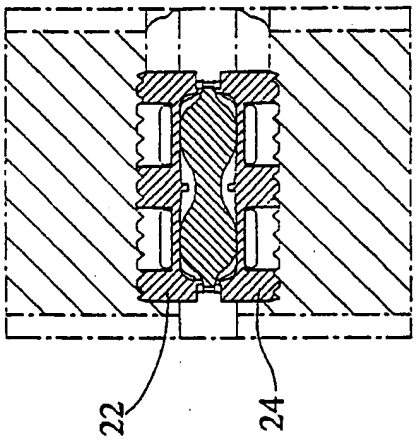



FIG. 4



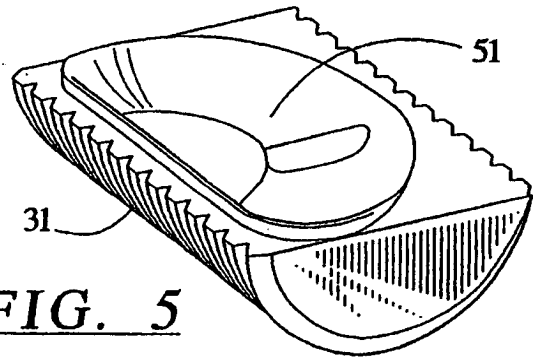



FIG. 5

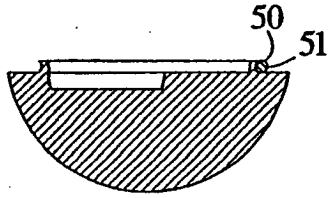
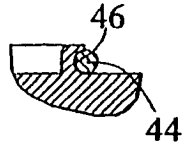



FIG. 8

FIG. 11



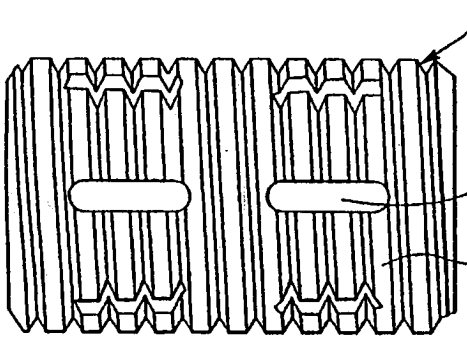




FIG. 6

FIG. 9

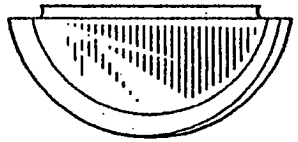
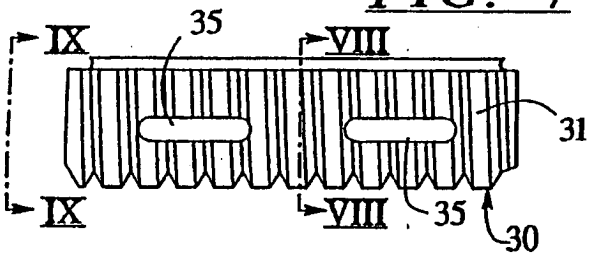


FIG. 12


FIG. 7



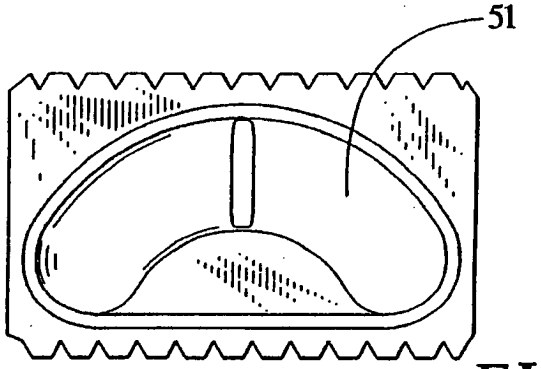
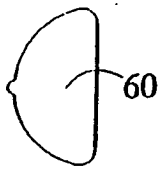




FIG. 10

FIG. 13



# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/20459

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) : A61F 2/44
US CL : 606/61; 623/16. 17
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61; 623/16-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST, WEST
Sarch Terms: threaded disc prosthesis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A, E | US 5,976,187 A (RICHELSOPH) 02 November 1999, col. 3 lines 39-47, col. 4 lines 8-10, and col. 6 lines 22-25. | 1, 4, 5, 11, 18, 20 |
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| A | US 5,645,598 A (BROSNAHAN, III) 08 July 1997, col. 3 lines 47-62, and col. 4 lines 14-17 and 38-41 | 1, 4, 5, 8, 10, 13-15, 18-20 |

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